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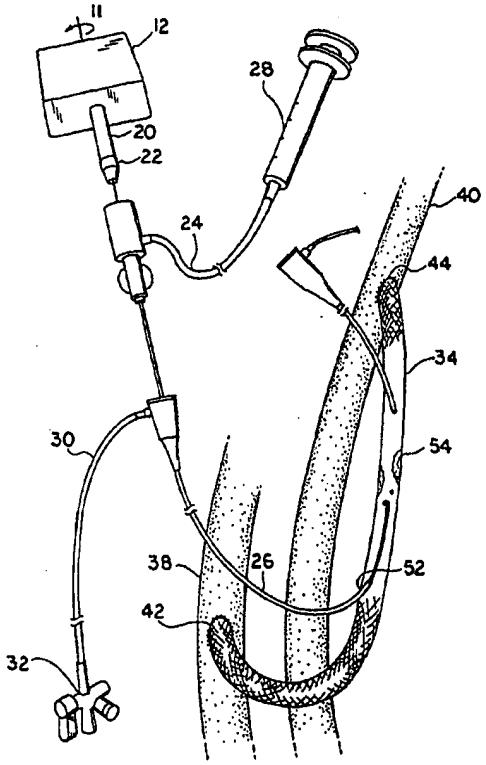
(57) Abstract

The method and apparatus for clearing lumens of thrombolytic material includes a motor having control means for operable using one hand holding the motor, an elongated wire connected to the motor and rotatable thereby, a catheter for enveloping a length of the wire and gripping means facilitating manual rotation of the catheter by one hand independently of the wire as the wire is rotated by the motor at a speed sufficient to create a standing wave in a portion of the wire extending from the catheter.



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ROTATIONAL THROMBECTOMY APPARATUS AND METHOD WITH STANDING WAVE

This patent application is based on and entitled to the filing date of United States provisional application 60/053,575 filed 24 July 1997 in the name of James F. McGuckin, Jr. and entitled "Rotational-Oscillatory Thrombectomy Device".

Field of the Invention

This invention relates to surgical apparatus for use in clearing recurring thrombosis of hemodialysis grafts.

Background of the Invention and Description of the Prior Art

Modern hemodialysis technology enables patients with chronic renal failure to live independently between dialysis treatments. Patients utilize this technology as a means of filtering the toxins from their blood by passing blood out of their body through a hemodialysis machine. The hemodialysis machine removes blood toxins by exposing the blood to dialyzing fluid across a semipermeable membrane, in effect creating an artificial kidney.

In order to properly process a patient's blood a graft is made, preferably in patient's arm. At the site of the graft a shunt is placed to connect an artery having a high rate of blood flow with a vein. The shunt provides a convenient inlet on the artery side for blood requiring dialysis filtration processing; the outlet is located on the vein side for return of dialysis processed blood from the hemodialysis station.

The dialysis shunt, while providing a convenient arrangement for hemodialysis processing, may become inoperable after a period of time due to stenosis caused by the high rate

of blood flow through the shunt and repetitive injury at the venous anastomosis. Typically, patients must have these constricting portions of the shunt widened periodically in order to continue hemodialysis processing through the shunt.

Shunt blockage is generally treated through a combination of surgical devices and/or pharmaceutical treatments; these techniques are often cost prohibitive and/or require an incision. For example, pharmaceutical treatments generally employ urokinase which, depending on the amount used, can cost upward of $350.00 per application and possibly cause bleeding complications.

Mechanical thrombolysis apparatus and methods for performing thrombolysis are known, being disclosed in United States patents 4,646,736 to Auth, 5,078,722 to Stevens and 5,695,507 to Auth, et al.

The apparatus disclosed in these patents seeks to penetrate thrombolytic structures by introducing, for example in the case of '507, a rotating core wire into the thrombus, seeking to withdraw fibrin from the thrombus into the rotating core wire thereby breaking up the network of the thrombus which is preventing blood flow.

Summary of the Invention

In one of its aspects this invention provides a method for clearing a surgical shunt or native body lumen of thrombolytic or other undesirable material by puncturing the shunt or native body lumen to form an aperture therein, inserting a rotatable hydrophilic wire into the interior of the shunt or body lumen through the aperture and rotating the wire within the shunt or

body lumen preferably at a speed sufficient to create a standing wave in an exposed portion of the wire within the shunt or body lumen to sweep the shunt or body lumen clear of thrombolytic or other undesirable material.

In another of its aspects this invention provides apparatus for clearing shunts and native body lumens of thrombolytic or other undesirable material where the apparatus preferably includes a motor preferably including control means which is preferably operable using one hand while holding the motor. The apparatus further preferably includes an elongated wire connected to the motor for rotation thereby where the wire is rotated preferably at speed sufficient to create a standing wave in the wire to rotationally sweep through the shunt or lumen to be cleared. Optionally and desirably the apparatus further preferably includes a catheter for enveloping a length of the wire and gripping means facilitating manual rotation of the catheter by one hand independently of the wire, as the wire is rotated by the motor, preferably at speed sufficient to create the standing wave in at least a portion of the wire extending from the catheter.

In further aspects of the invention the apparatus preferably includes manually actuable means for selectably connecting the wire to the motor.

Preferably the wire is hydrophilic, is not permanently deformable at room temperature and may be either braided or a single filament; a braided wire is most preferred.

Preferably the extremity of the wire remote from the catheter either is angularly disposed with respect to the

remainder of the wire or is J-shaped, curving back towards the motor.

In another of the apparatus aspects of the invention, the extremity of the catheter remote from the motor may be preferably angularly disposed with respect to the remainder of the catheter. The catheter is preferably sufficiently resistant to twisting that torque manually applied to the catheter proximate the motor results in corresponding angular rotary movement of the extremity of the catheter remote from the motor.

When the wire is in the form of a single filament, the extremity of the filament extending from the catheter is preferably at an angle to the axis of the filament.

In yet another of its aspects the invention preferably provides first means communicating with the interior of the catheter for selectably supplying or exhausting fluid to and from the catheter interior.

In yet another aspect of the invention the apparatus may preferably further include a sheath enveloping the catheter and a conduit communicating with the interior of the sheath for selectably supplying or exhausting fluid to and from the sheath interior, externally of the catheter. When such a second conduit is present, the second conduit is preferably movable longitudinally along the wire with the sheath.

The gripping means for the catheter is preferably fixedly connected to the first conduit means communicating with the catheter interior and is preferably rotatable unitarily with the catheter about the wire.

In yet another of the apparatus aspects of the invention,

the second conduit, the sheath, the motor, the catheter, the first conduit and the wire are all preferably manually disassemblable from one another preferably without use of tools.

In yet another apparatus aspect of the invention, the apparatus preferably further includes a housing for the motor and the control means, where the housing is adapted for grasping by one hand for operator control of the apparatus and where the wire passes through the housing and emerges from an opposite side thereof.

The motor may be electrically, pneumatically or hydraulically powered; electrical power is preferable.

In yet another of its aspects, the method of the invention further includes moving the rotating wire, with a vibrational node extant therein, axially along the lumen to rotationally sweep thrombolytic or other undesirable material from the shunt or lumen in a circumferentially sweeping action.

In a method aspect of the invention, when the rotatable hydrophilic wire is inserted into the interior of the shunt or lumen there is desirably provided a catheter surrounding the hydrophilic wire from which the wire extends into the interior of the shunt or lumen through the aperture.

In a method aspect of the invention, a rotating step desirably further includes rotating the wire but not the catheter within the shunt or lumen at a speed at which the wire forms at least one vibrational node in the portion of the wire extending from the catheter tip within the shunt or lumen.

Most desirably the method aspect of the invention further includes rotating the wire but not the catheter within the shunt

or lumen at a speed from about 100 revolutions per minute to about 10,000 revolutions per minute.

In the method aspect of the invention, wire rotation may be performed manually or by a motor rotating the wire within the shunt or lumen. In either event the wire is preferably rotated at a speed at which the wire forms at least one vibrational node in the portion of the wire within the lumen, most preferably in the portion of the wire extending outwardly of the catheter. The wire is desirably moved along the shunt or lumen longitudinally by moving the motor; orientation of the wire within the shunt or lumen is desirably controlled by rotating the catheter, preferably manually.

The motor is most preferably a hand-held motor; moving the wire along the shunt or lumen is most preferably performed by manually moving the motor. Controlling orientation of the wire is preferably performed by manually rotating the catheter. All of these manual operations are preferably performed using only one hand.

In a method aspect of the invention, the rotating step is preferably performed by rotating the wire within the shunt or lumen along the length of the shunt or lumen for a time sufficient to macerate thrombolytic material within the shunt or lumen and thereby produce a standing column of liquified material therewithin.

In another of its aspects, the invention provides a method for clearing a surgical shunt connecting an artery to a vein and associated portions of said artery and vein of thrombolytic material by initially inserting a needle through a patent's skin

and into the shunt, inserting a first wire through the needle, sensing whether the first wire is in the shunt preferably by tactile sensation received via the wire, x-ray inspecting skin preferably where the needle was inserted to determine whether the wire is within the shunt, removing the needle when the wire is determined to be within the shunt, placing a first catheter over the first wire with a catheter discharge orifice within the shunt, removing the first wire leaving the first catheter with the discharge end within the shunt, inserting a second wire through the first catheter into the interior of the shunt, removing the first catheter from the shunt, inserting a sheath over the second wire and into the shunt, removing the second wire, inserting a rotatable instrument wire and an associated surrounding catheter through the sheath and into the shunt, supplying lubricating fluid to the associated catheter interior to lubricate the instrument wire for rotation within the associated catheter, sweepingly rotating the instrument wire, but not the associated catheter, through the shunt to liquify thrombolytic material therein, removing the instrument wire and associated catheter from the sheath, applying suction to the sheath to remove liquid thrombolytic material from the shunt interior, injecting anti-coagulant into the shunt interior through the sheath, removing the instrument wire from the associated catheter, disconnecting the instrument wire from a drive motor associated therewith, re-inserting the instrument wire without the associated catheter through the sheath into the shunt interior and through any blockage at the vein end of the shunt and into the vein, placing an angioplasty balloon over the

instrument wire, pushing the angioplasty balloon into position within venous anastomosis at vein-shunt juncture, removing the wire leaving the angioplasty balloon in position within the venous anastomosis at vein-shunt juncture, injecting radiology contrast dye through a lumen of the balloon vacated by removal of the instrument wire therefrom, observing dye travel through the vein to the patient's heart to reveal any venous blockages, inserting the instrument wire back into the balloon lumen, inflating the balloon to crush any venous anastomosis and open shunt-vein juncture, removing the balloon and instrument wire from the sheath, inserting a second sheath between the position of first sheath insertion and shunt-vein juncture into a shunt interior region cleansed of thrombolytic material, re-inserting the instrument wire without the associated catheter through the second sheath into the shunt through any blockage at shunt-artery juncture, placing an angioplasty balloon over the wire, pushing the balloon into position within arterial anastomosis at artery-shunt juncture, removing the wire leaving the angioplasty balloon in position, injecting contrasting radiology dye through the balloon lumen vacated by the wire, observing travel of the dye through the artery to the heart thereby revealing any arterial blockages, inserting the instrument wire back into the balloon lumen, inflating the balloon to crush any arterial anastomosis and thereby open shunt-artery juncture, removing a platelet plug and residual arterial anastomosis from the shunt-artery juncture by pulling on the balloon and, finally, removing the balloon, wire and sheath from the patient.

The apparatus may include a hydrophilic wire which is placed into the shunt access port, advanced to the blockage within a lubricated catheter which is steerable and is rotated, with the same hydrophilic wire extending beyond the tip of the directional catheter about its longitudinal axis thereby separating material adhering to the inside surface of the dialysis shunt and mechanically macerating the thrombus.

During rotation, the exposed length of the hydrophilic wire preferably begins to periodically flex in an oscillatory fashion, forming a standing wave contributing to the ability to clear the length of the shunt. The maximum deflection points of the rotating wire allow shunt cleansing by rotating the oscillatory wire providing a scouring action clearing the wall of adherent thrombus while also breaking up clots within the graft. The tip of the hydrophilic wire is preferably translated into and out of the thrombus within the shunt thereby mechanically disrupting and dissolving clots in both directions of translation and hence decreasing time necessary to complete thrombolysis. The wire can then be disassembled from the device and used as necessary to complete a shunt renewal procedure.

In another of its aspects the invention provides a method for clearing dialysis shunts. A catheter entrance port is prepared for reception of the hydrophilic wire apparatus. The tip of the wire is advanced into the clot; the wire is rotated preferably by an electric motor such that the hydrophilic wire rotates about its longitudinal axis within a lubricated catheter, with rotation of the wire creating an oscillatory flexing of the hydrophilic wire along substantially its length outside of the

lubricating directional catheter.

Brief Description of the Drawings

Figure 1 which is presented as Figures 1(a) through 1(f) in separate pages, is a flow chart of a surgical method on invention;

Figure 2 is a partially exploded side sectional view of one embodiment of apparatus manifesting aspects of the invention.

Figure 3 is an unexploded top view of the apparatus shown in Figure 2.

Figure 4 is a top view of a second embodiment of apparatus in which the rotating wire extends through the handpiece.

Figure 5 illustrates apparatus in accordance with the invention in place within a dialysis shunt.

Figure 6 is a broken view illustrating an embodiment the catheter with a bent end to facilitate directional control of the wire.

Figure 7 is a schematic illustrating depicting hand operation of the apparatus in accordance with the invention.

Figure 8 depicts rotation of the wire in the catheter.

Figure 9 shows the standing wave formed by the wire resident in this shunt.

Figures 10 through 13 are alternative tip configurations of the rotating wire.

Detailed Description of the Preferred Embodiment

This invention provides a surgical apparatus and method for clearing of dialysis shunt blockages in hemodialysis patients.

Part of the surgical apparatus rotates, separating the blockage material from the inside surface of the dialysis shunt while macerating any thrombus within the shunt. Thus, the shunt is cleared with a minimum of trauma and without use of costly pharmaceuticals.

Referring to Figure 2 through 4, the surgical apparatus in accordance with the invention is generally designated 10 and includes a rotatable hydrophilic wire 16 and with a deformed tip 25.

Wire 16 rotates about an axis 11. Rotation of wire 16 of apparatus 10 is preferably performed by an electric motor 12, equipped with a mechanical hand control. However, wire 16 may be turned by pneumatic or hydraulic motor or even manually.

Hydrophilic wire 16 is preferably selected such that it rotates and oscillates so that a maximum number of points of maximum deflection between nodes of the standing wave reach the inner shunt wall to scour and remove adherent thrombus.

Apparatus 10 may be utilized to perform a number of procedures. Wire 16 is advanced through a catheter entrance port 52 of a dialysis shunt 34. Wire 16 is advanced along the interior surface of shunt 34 in the direction of a blockage; the tip of wire 16 may be translated into a thrombus, extending out of a distal tip of a directional lubricated catheter by the operator handling apparatus 10. As wire tip 25 rotates about axis 11, an adherent clot is separated from the interior surface 54 of dialysis shunt 34 by rotating contact of deformable wire tip 25 as well as oscillatory flexing of wire 16 in both directions along the longitudinal axis of the shunt as a standing

wave is desirably formed in wire 16.

The clot material is broken up by rotation of wire 16 sufficiently such that passage of clot material does not present a physiological problem for the patient; alternatively the clot material may be aspirated out of the shunt via an access port.

Referring to Figures 2, 3 and 4, motor 12 preferably includes control means for the motor which is operable using the hand which holds the motor. One hand preferably grasps motor 12 and operates the control means therefor. Elongated wire 16, which is also sometime called the instrument wire, is connected to motor 12 for rotation thereof by motor 12. A catheter 18 envelops wire 16. The tubular gripping means 20 fits about catheter 18 to facilitate manual rotation of catheter 18. A manually chuck 22 provides means for selectively connecting wire 16 to motor 12.

A first conduit 24 is provided communicating with the interior of catheter 18 via a first fitting 28 which connects the first conduit to the interior of catheter 18. A second conduit 30 provides communicating with the interior of sheath 26 via a second fitting 32 providing such connection. A surgical shunt 34 is provided between the vein and artery of the patient to under dialysis.

The apparatus illustrated in Figures 2 and 3, motor 12 turns wire 16 while catheter 18 is rotated by manually actuating gripping means 20. Gripping means 20 together with fitting 28 is moveable axially along wire 16 to control the amount of wire 16 which is exposed beyond the extremity of catheter 18.

In the embodiment of the apparatus illustrated in Figure 4, wire 16 desirably extends out the rear of a housing for motor 12. This facilitates withdrawal of wire 16 to and from the shunt, artery and vein of interest.

In the embodiment illustrated in Figure 4, a second fitting 32 ha not been provided nor has a second conduit been provided for input of fluid to interior of sheath 26.

The portion of wire 16 which is exposed beyond the tip of catheter 18 is designated 50 in the drawings.

Not only is first fitting 28 and first conduit 24 moveable together with gripping means 20 with catheter 18 respecting wire 16 but also second fitting 32 and second conduit 30 are preferably moveable with sheath 26 relative to wire 16.

The extremity of wire 16 remote from the catheter, denoted 50 in the drawings, may be angularly disposed with respect to the remainder of the wire. Alternatively, extremity 50 and wire 16 remote from the tip bend of the catheter may be J shaped.

The extremity portion of catheter 18 remote from motor 12 may be angularly disposed with respect to the remainder of the catheters; this configuration helps positioning of exposed portion of wire 16 by manual movement of catheter 18.

Preferably, second conduit 30, second fitting 32, sheath 26, motor 12, catheter 18, first conduit 24, fitting 28 and wire 16 are all manually disassemblable from one another.

Figure 5 depicts the apparatus according to one of the aspects of the invention in place within a surgical dialysis shunt where the shunt is denoted generally 34 and connects a vein 38 with an artery 40. Vein shunt-juncture is denoted 42 while

artery shunt-juncture is denoted 44.

In the practice of the method of the invention for clear a lumen or shunt of thrombolytic material, rotatable hydrophilic wire 16 is inserted into the interior of the shunt or lumen through a suitable aperture which may be created by puncturing the shunt or lumen with a needle. The wire is then rotated within the lumen at a speed of which the wire forms at least one vibrational node in the portion of the wire within the lumen; this configuration of the wire is depicted in Figure 8. The wire is preferably moved with the vibrational nodes therein axially along the lumen to rotational sweep the thrombolytic material from the lumen; this motion is depicted by arrow A in Figure 8. Preferably not only the wire but also the catheter extremity is inserted into the lumen through the selected aperture. When the wire is rotated, the catheters maintain stationary relative to the wire and are manually manipulated in order to guide the wire through the shunt and, as necessary, into the shunt-vein or shunt-artery juncture and in the course of performing the most comprehensive aspect of the method of the invention, into the vein or artery to cleanse thrombolytic material therefrom.

The wire is preferably rotated at a speed at which the wire forms at least one vibrational node and the portion 55 of wire 16 extending from catheter 18 into the lumen or shunt. All of this is performed while grasping motor 12 with one hand. Motor 12 preferably has a control by the thumb or forefinger of the hand holding motor 12 so that by using a single hand, the physician or other attending health professional can control not only rotation of wire 16 but also position of catheter 18 thereby

controlling the position of wire 16 within the shunt or other lumen to be cleansed. This frees the second hand of the operator to supply medication or lubricant through conduits 24 or 30 or to perform other activity.

As illustrated in Figure 8, the wire 16 is preferably braided and is rotated in a direction to resist untwisting of the braid.

Manual manipulation of the catheter is illustrated in Figure 7. The angular tip of the catheter 18 when rotated by hand as illustrated permits accurate and close positioning of exposed portion 50 of rotating wire 16. The preferred angular orientation of catheter 18 is illustrated in Figure 6.

Catheter 18 is preferably sufficiently resistive to twisting the torque manually applied to the catheter approximate to motor, for example via gripping means 20, causes corresponding angular movement of the extremity of the catheter remote from the motor.

While a braided wire is preferable, a filament wire may be used.

The motor is preferably operated to rotate the wire at a speed to create at least one vibrational node therein. The rotation speed of the wire may be from about 100 revolutions per minute to about 10,000 revolutions per minute. The motor used to turn the wire is desirably electrically powered but may also be pneumatically or hydraulically powered. Also, the wire 16 may be rotated manually if necessary.

Not only does the invention have utility with respect to cleansing of dialysis shunts and the juncture of such shunts with veins and arteries, the invention also has utility in cleansing

such arteries and veins blockages all the way to the heart.

This comprehensive shunt/vein/artery cleansing procedure begins with inserting a needle through skin and into the shunt. The next step is that of inserting a small wire through the needle. The next step is that of using the tactile sensation transmitted by the wire, determine whether the wire is in the shunt. The next step is that of inspecting the skin site with x-ray to determine position of the wire and whether it is within the shunt.

The next step is that of removing the needle when the wire is determined to be in the shunt interior. The next step is that of placing a small catheter over wire with the discharge orifice within the shunt. The next step is that of removing the wire leaving the catheter with its discharge end within the shunt.

The next step is that of inserting a larger wire through the catheter into the shunt interior. The next step is that of removing the catheter. The next step is that of inserting a sheath over the larger wire and into the shunt.

The next step is that of removing the larger second wire. The next step is that of inserting an instrument wire and the catheter through the sheath. The next step is that of supplying lubricating fluid to the catheter interior.

The next step is that of rotating the wire, but not the catheter, and sweeping through the graft to liquify thrombus material therein. The next step is that of removing the instrument wire and the catheter from sheath. The next step is that of applying suction to the sheath to remove liquid thrombus material from the shunt.

The next step is that of inserting a anti-coagulant into the shunt through sheath. The next step is that of removing the instrument wire from the catheter. The next step is that of disconnecting the instrument wire from the motor.

The next step is that of re-inserting the instrument wire without the catheter through the sheath into the shunt, through any blockage at the shunt end into the vein. The next step is that of placing an angioplasty balloon over the wire. The next step is that of pushing a balloon into position within venous anastomosis at vein-shunt juncture. The next step is that of removing the wire leaving the angioplasty balloon in position.

The next step is that of injecting contrast radiology dye through the balloon lumen vacated by the wire. The next step is that of observing dye travel through the vein to the heart using a fluoroscope revealing any additional venous blockages. The next step is that of inserting a wire back into the balloon lumen. The next step is that of inflating the balloon to crush venous anastomosis and open the shunt-vein juncture.

The next step is that of removing the balloon and wire. The next step is that of inserting a second sheath between position of the first sheath insertion and shunt-vein juncture, into clean shunt region. The next step is that of re-inserting the instrument wire without the catheter through the sheath into the shunt, through any blockage at the shunt-artery juncture. The next step is that of placing an angioplasty balloon over the wire.

The next step is that of pushing the balloon into position within arterial anastomosis at artery-shunt juncture. The next

step is that of removing the wire leaving the angioplasty balloon in position. The next step is that of injecting contrast radiology dye through the balloon lumen vacated by the wire.

The next step is that of observing dye travel through the artery to the heart using a fluoroscope and revealing any additional arterial blockages. The next step is that of inserting a wire back into the balloon lumen.

The next step is that of inflating the balloon to crush any arterial anastomosis and open the shunt-artery juncture. The next step is that of removing a platelet plug and residual arterial anastomosis from the shunt-artery juncture by pulling on the balloon. The final step is that of removing the balloon, wire and the sheath.

CLAIMS

I claim the following:

1. Apparatus for clearing lumens of thrombolytic material, comprising:
   a. a motor including control means therefor operable using one hand holding said motor;
   b. an elongated wire connected to said motor for rotation thereof by said motor;
   c. a catheter for enveloping a length of said wire; and
   d. gripping means facilitating manual rotation of said catheter by said one hand independently of said wire as said wire is rotated by said motor at a speed sufficient to create a standing wave in a portion of said wire extending from said catheter.

2. Apparatus of claim 1 wherein the extremity of said catheter remote from said motor is angularly disposed with respect to the remainder of said catheter.

3. Apparatus of claim 1 wherein the extremity of said wire remote from said catheter is J-shaped.

4. Apparatus of claim 1 further comprising a housing for said motor and said control means, adapted for grasping by said one hand, wherein said wire passes through said housing and emerges from opposite sides thereof.

5. Apparatus for clearing bodily passageways of thrombolytic material, comprising:

   a. one hand manipulable means for providing rotary motion output;

   b. an elongated wire connected to said rotary motion output means for rotation thereby;

   c. a catheter for enveloping a length of said wire; and

   d. gripping means facilitating manual rotation of said catheter by said one hand independently of said wire as said wire is rotated to create a standing wave in a portion extending from said catheter.

6. A method for clearing a lumen of thrombolytic material, comprising:

   a. inserting a rotatable hydrophilic wire into the interior of said lumen through said aperture;

   b. rotating said wire within said lumen at a speed at which said wire forms at least one vibrational node in the portion of said wire within said lumen.

7. The method of claim 6 further comprising:

   a. providing a motor for rotating said wire within said lumen at a speed at which said wire forms at least one vibrational node in the portion of said wire within said lumen;

   b. moving said wire along said lumen by moving said motor; and

   c. controlling orientation of said wire within said lumen

by rotating said catheter.

8. The method of claim 6 wherein said motor is a hand held motor; moving said wire along said lumen is performed by manually moving said motor; and controlling orientation of said wire within said lumen is performed by manually rotating said catheter.

9. The method of claim 8 further comprising performing all of said manual operations with one hand.

10. A method for clearing a surgical lumen or similar body lumen of thrombolytic material, comprising:

a. puncturing said lumen to form an aperture therein;

b. inserting a rotatable hydrophilic wire into the interior of said lumen through said aperture;

c. rotating said wire within said lumen at a speed sufficient to create a standing wave in the portion of said wire within said lumen.

AMENDED CLAIMS

[received by the International Bureau on 31 December 1998 (31.12.98); new claims 11-21 added; remaining claims unchanged (3 pages)]

11. Apparatus for cleansing a body lumen of thrombolytic material by rotary sweeping of an elongated wire having standing wave form within said lumen as said wire moves axially in said lumen, comprising:

a. a rotatable elongated wire having a tip portion which is asymmetrical respecting the wire axis;

b. a motor including control means therefor operable using one hand holding said motor for rotating said wire at speed sufficient to form a standing wave having at least one node in said wire resulting from the asymmetrical configuration of the wire tip remote from said motor, movement of said motor in the direction of elongation of said wire moving said wire axially within said lumen as said wire has said standing wave formed therein to circumferentially sweep said lumen clear of thrombolytic material;

c. a catheter for enveloping a length of said wire short of said asymmetrical tip;

d. gripping means facilitating manual rotation of said catheter by said hand holding said motor independently of said wire as said wire is rotated by said motor to form said standing wave in at least a portion of said wire extending from said catheter.

12. Apparatus of claim 11 wherein said wire is twisted and said motor rotates said wire in a direction opposite to the twist.

13. Apparatus of claim 11 wherein said wire tip is disposed at an angle respecting the axis of rotation of the wire.

14. Apparatus of claim 11 wherein said wire tip is J-shaped and extends back towards said motor.

15. Apparatus of claim 11 further comprising:

a. conduit means communicating with the interior of said catheter for selectably supplying or exhausting fluid to and from the catheter interior;

b. a tubular sheath enveloping said catheter;

c. second conduit means communicating with the interior of said sheath for selectably supplying or exhausting fluid to and form the sheath interior, exterior of the catheter;

d. said wire tip being disposed at an angle respecting the axis of rotation of the wire and extending axially outwardly beyond said catheter and said sheath.

16. Apparatus of claim 15 wherein said wire tip is disposed at an angle respecting the axis of rotation of the wire.

17. Apparatus of claim 15 wherein said wire tip is J-shaped and extends back towards said motor.

18. Apparatus of claim 15 further comprising said gripping means being fixedly connected to said conduit means communicating with said catheter.

19. Apparatus of claim 15 wherein said conduits, said motor, said catheter and said wire are all manually disassemblable one from another without use of tools.

20. Apparatus of claim 11 further comprising a housing for said motor and said control, said housing being adapted for grasping by one hand for operator control of the apparatus, wherein a portion of said wire remote from said catheter passes through said housing and emerges therefrom in a direction opposite that of said catheter.

21. Apparatus of claim 15 further comprising a housing for said motor and said control, said housing being adapted for grasping by one hand for operator control of the apparatus, wherein a portion of said wire remote from said catheter passes through said housing and emerges therefrom in a direction opposite that of said catheter and said sheath.

Statement Under Article 19

Dear Sirs:

The cornerstone of this invention, as recited in the original and newly added claims, is provision of a rotating wire which has a standing wave form, for use in a naturally occurring body lumen or a surgically created shunt lumen, to clear the lumen of thrombolytic material by rotationally sweeping the shunt circumferentially to clear it of thrombolytic material as the wire moves axially through the lumen. The standing wave in the wire, which facilitates the sweeping action to cleanse the lumen as the wire is rotated, results from the rotation of the wire with the wire having an asymmetrical tip at the end of the wire opposite the wire end rotated by a motor. Rotary sweeping by a wire having a standing wave configuration is the action which cleanses the lumen of the thrombolytic material.

The asymmetrical tip of the wire may be bent with respect to the wire axis or may be J-shaped in a manner curving back towards the motor, away from the wire extremity.

The invention most desirably and effectively removes the thrombolytic material by contact of one or more locales of maximum deflection of the rotating wire and the inner surface of the lumen wall to scour and remove adherent thrombus therefrom.[1] Oscillatory flexing of the wire along the longitudinal axis of the lumen[2] as the wire rotates causes the wire to assume a standing wave form permitting the desired circumferential sweeping action and scouring the inner surface of the lumen. As

such, the preferred and dominant means by which the invention removes undesirable thrombolytic material is via lateral, transverse or circumferential contact with the undesirable thrombolytic material, as that material is adherent to the inner wall surface of the lumen being axially traversed by the wire. Most preferably, as the undesirable thrombolytic material is swept and scoured from the inner wall surface of the lumen, the material is broken sufficiently that passage of the broken thrombolytic material does not present any problem for the patient.

This is to be contrasted to prior means for removal of thrombolytic material which work by axially or longitudinally contacting and penetrating thrombolytic material which is encountered as the means axially traverses the length of the lumen of interest. With such prior means, if the thrombolytic material is not of an amount and configuration to at least substantially block the lumen of interest, the material removal means may pass longitudinally by the thrombolytic material without removing any significant part of the undesirable thrombolytic material from the lumen. Moreover, when using such prior means, it is necessary to repeatedly remove the means from and reinsert the means into the patient's lumen, since the thrombolytic material is conventionally collected on the means as the means is moved axially within the lumen to encounter the thrombolytic material to be removed.

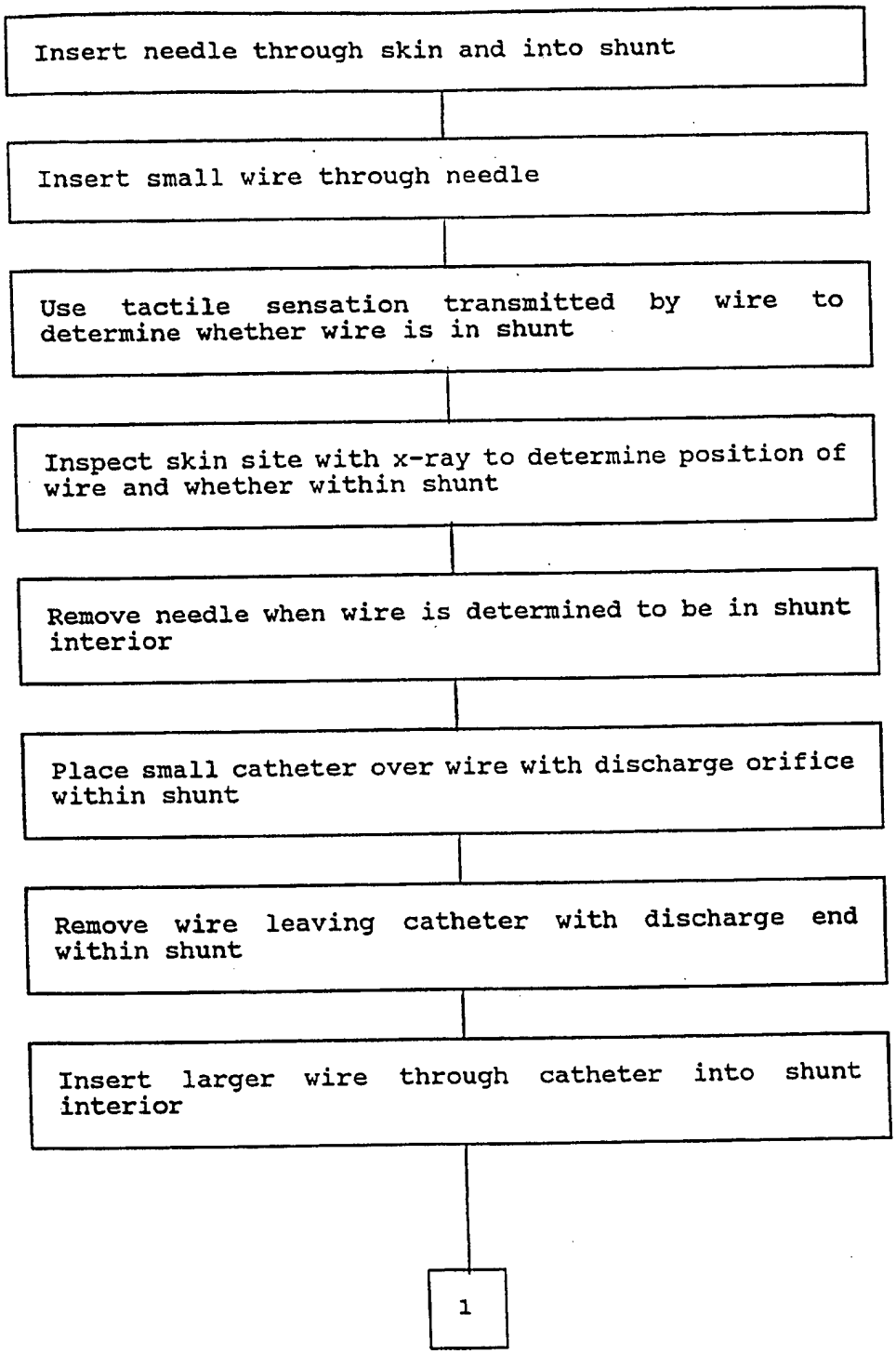
Insert needle through skin and into shunt
Insert small wire through needle
Use tactile sensation transmitted by wire to determine whether wire is in shunt
Inspect skin site with x-ray to determine position of wire and whether within shunt
Remove needle when wire is determined to be in shunt interior
Place small catheter over wire with discharge orifice within shunt
Remove wire leaving catheter with discharge end within shunt
Insert larger wire through catheter into shunt interior
1

Figure 1(a)

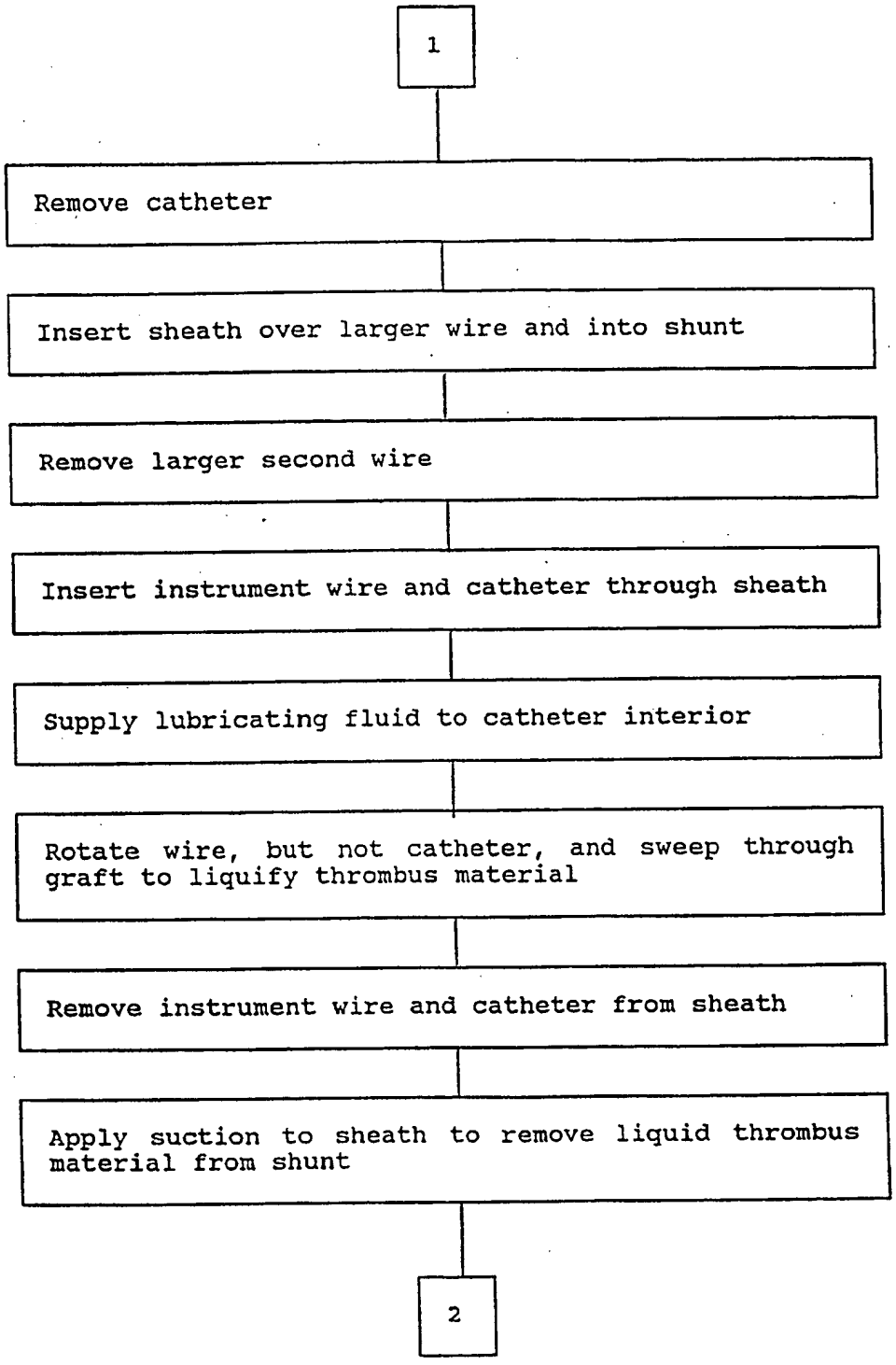
1
Remove catheter
Insert sheath over larger wire and into shunt
Remove larger second wire
Insert instrument wire and catheter through sheath
Supply lubricating fluid to catheter interior
Rotate wire, but not catheter, and sweep through graft to liquify thrombus material
Remove instrument wire and catheter from sheath
Apply suction to sheath to remove liquid thrombus material from shunt
2

Figure 1(b)

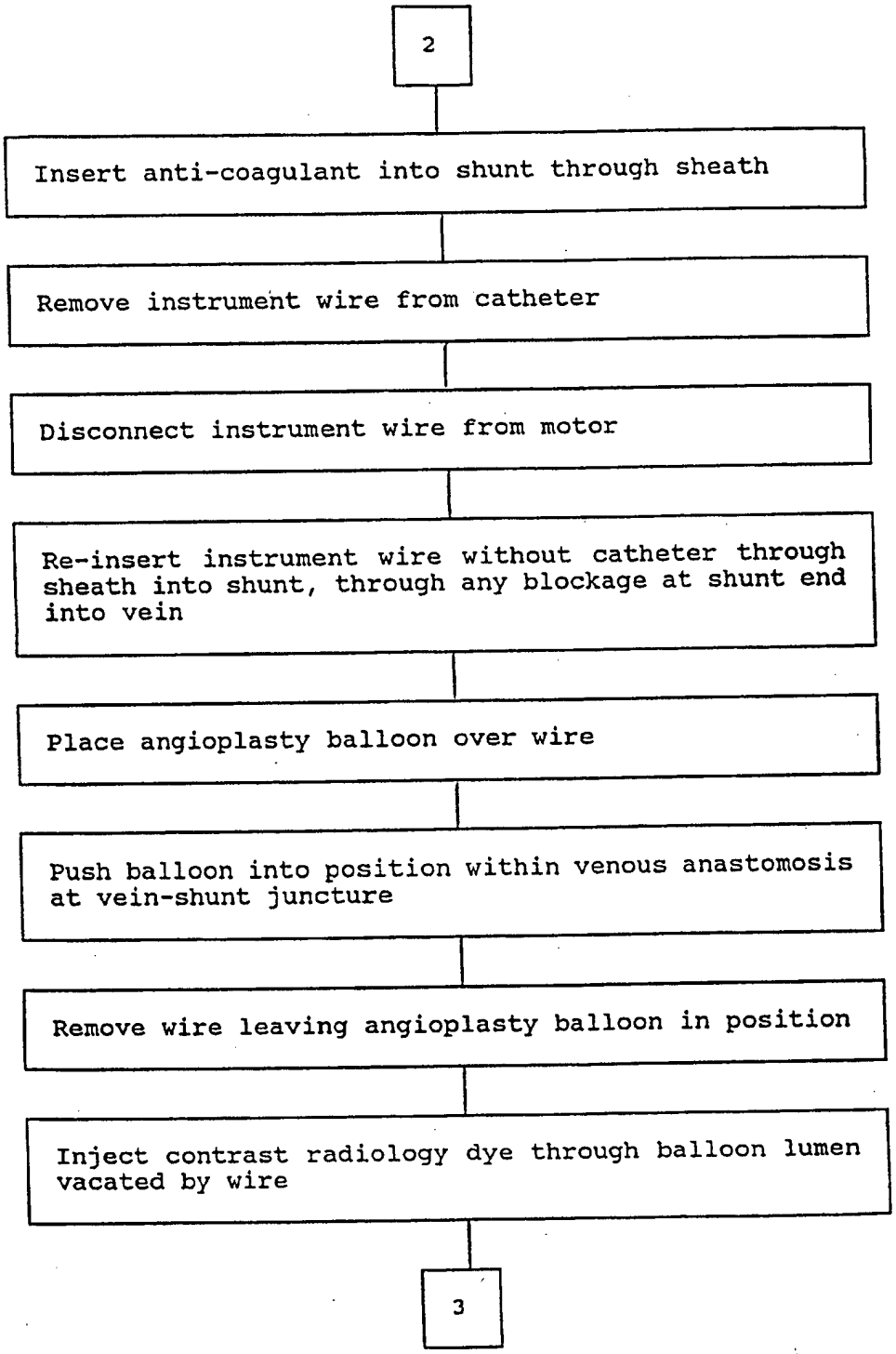
2
Insert anti-coagulant into shunt through sheath
Remove instrument wire from catheter
Disconnect instrument wire from motor
Re-insert instrument wire without catheter through sheath into shunt, through any blockage at shunt end into vein
Place angioplasty balloon over wire
Push balloon into position within venous anastomosis at vein-shunt juncture
Remove wire leaving angioplasty balloon in position
Inject contrast radiology dye through balloon lumen vacated by wire
3

Figure 1(c)

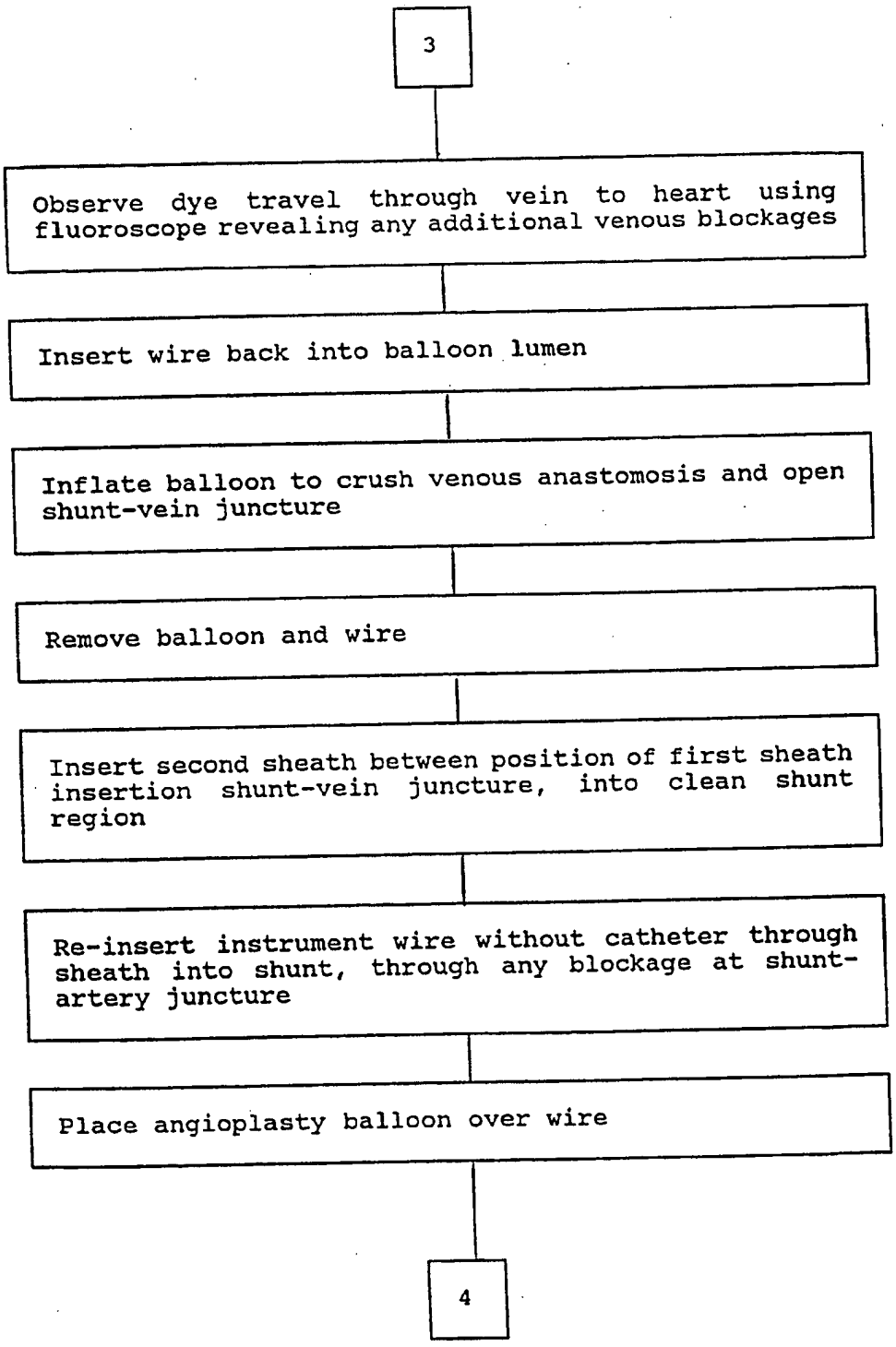
3
Observe dye travel through vein to heart using fluoroscope revealing any additional venous blockages
Insert wire back into balloon lumen
Inflate balloon to crush venous anastomosis and open shunt-vein juncture
Remove balloon and wire
Insert second sheath between position of first sheath insertion shunt-vein juncture, into clean shunt region
Re-insert instrument wire without catheter through sheath into shunt, through any blockage at shunt-artery juncture
Place angioplasty balloon over wire
4

Figure 1(d)

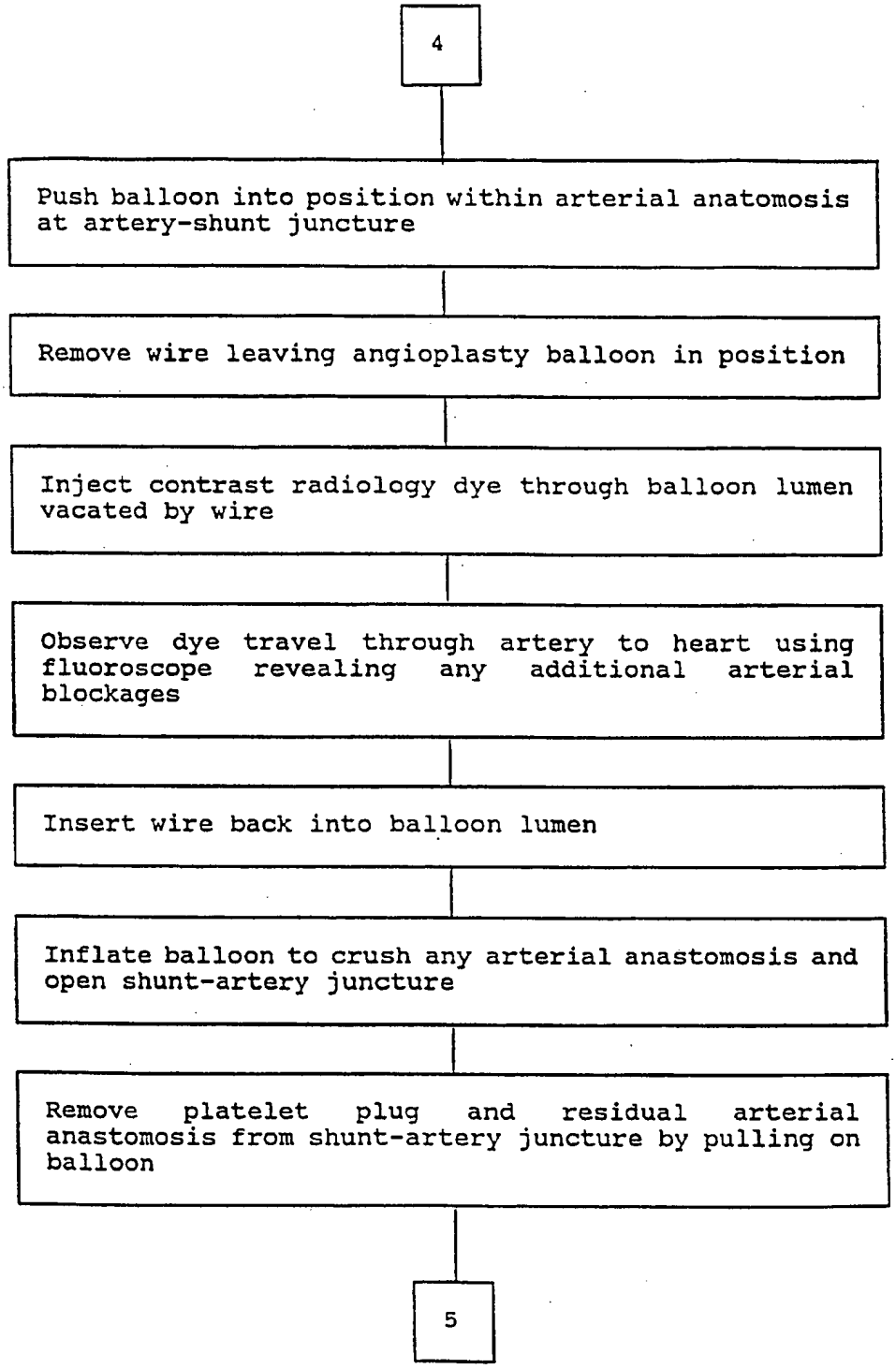
4
Push balloon into position within arterial anatomosis at artery-shunt juncture
Remove wire leaving angioplasty balloon in position
Inject contrast radiology dye through balloon lumen vacated by wire
Observe dye travel through artery to heart using fluoroscope revealing any additional arterial blockages
Insert wire back into balloon lumen
Inflate balloon to crush any arterial anastomosis and open shunt-artery juncture
Remove platelet plug and residual arterial anastomosis from shunt-artery juncture by pulling on balloon
5

Figure 1(e)

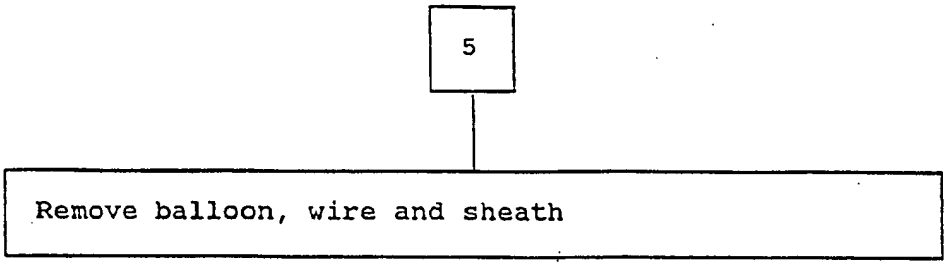

Figure 1(f)

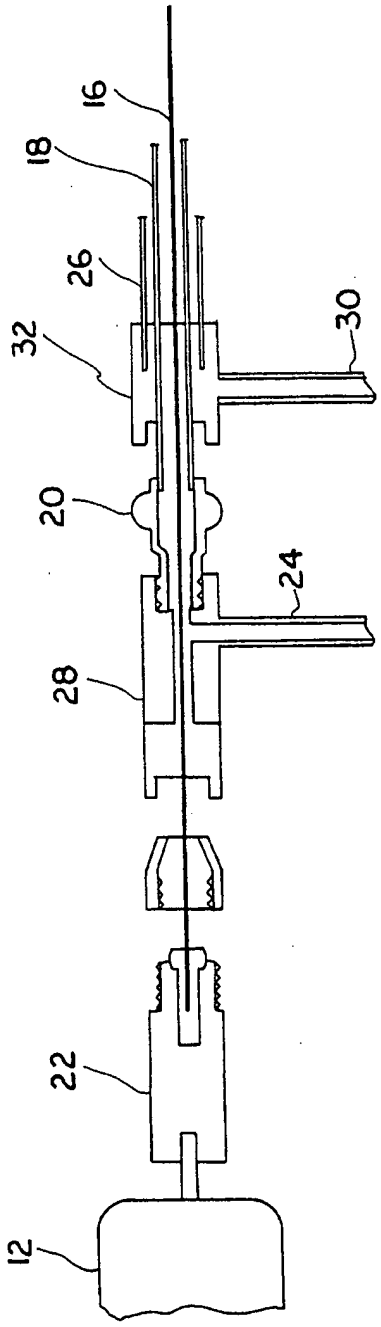

FIG. 2

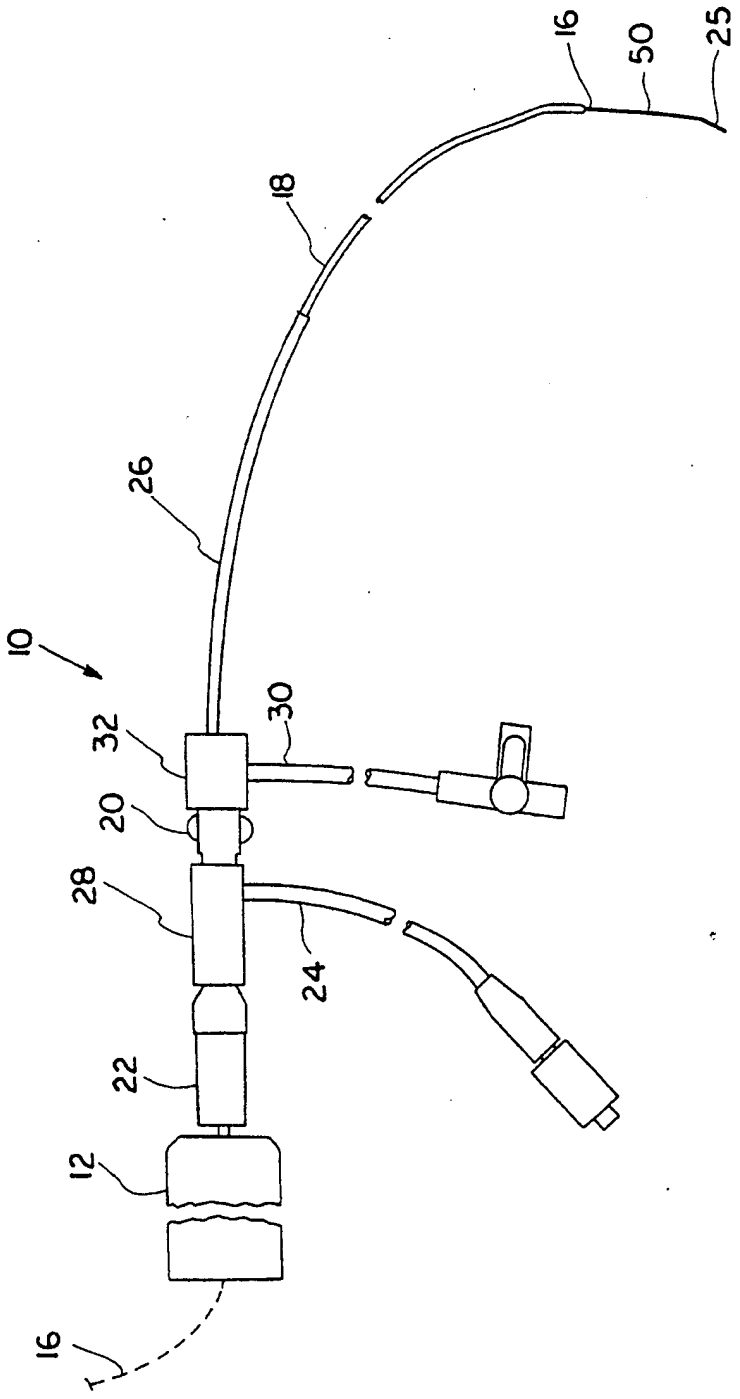

FIG. 3

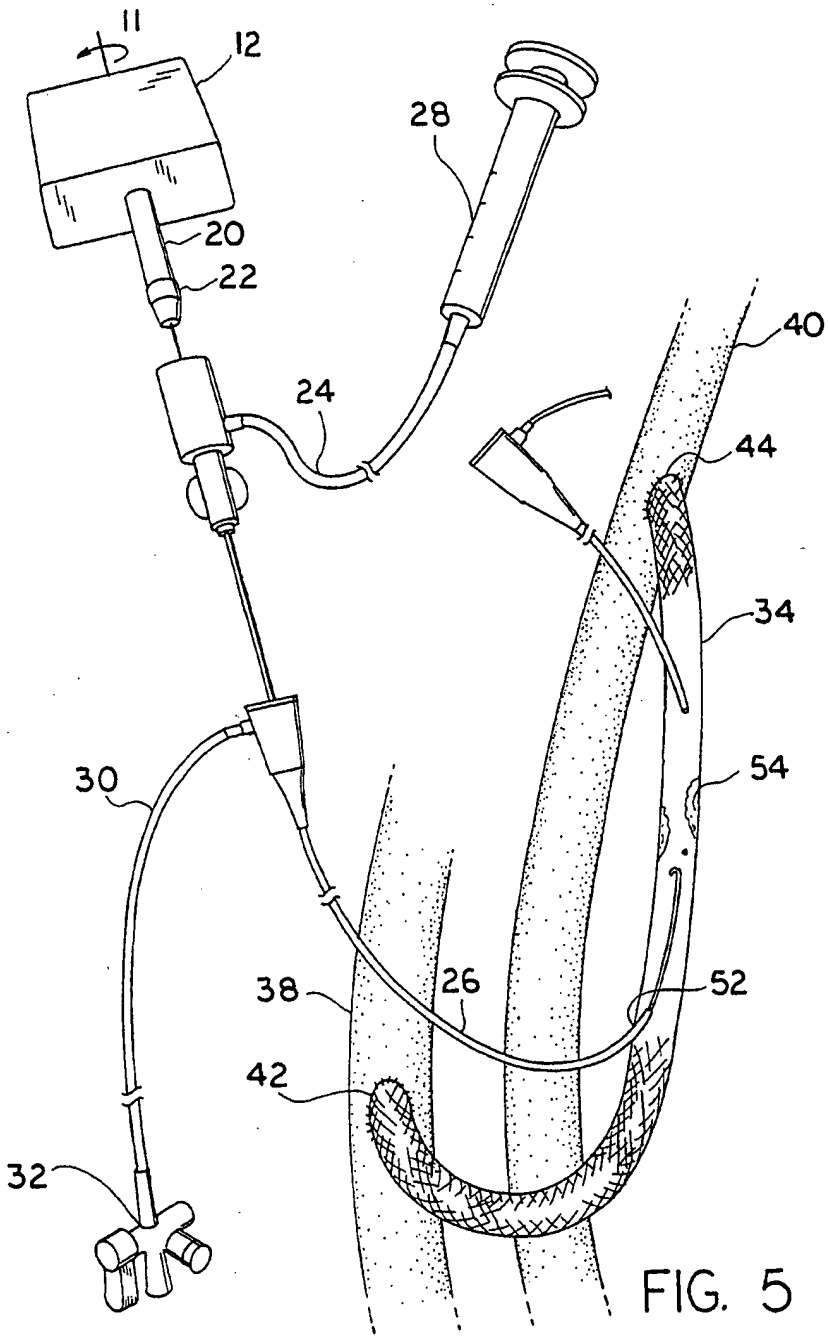

FIG. 5

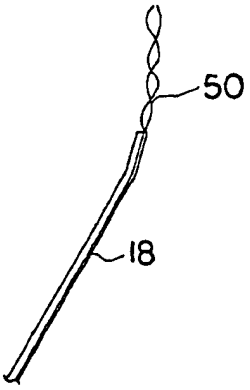

FIG. 6

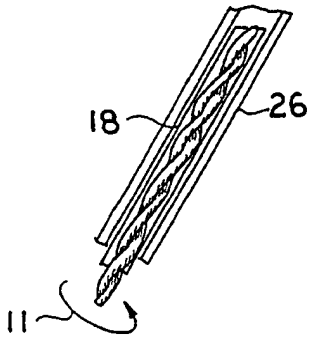

FIG. 8

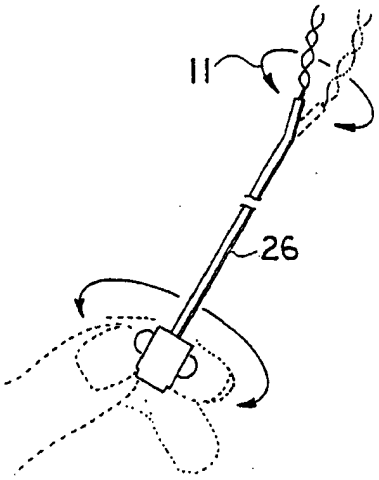

FIG. 7

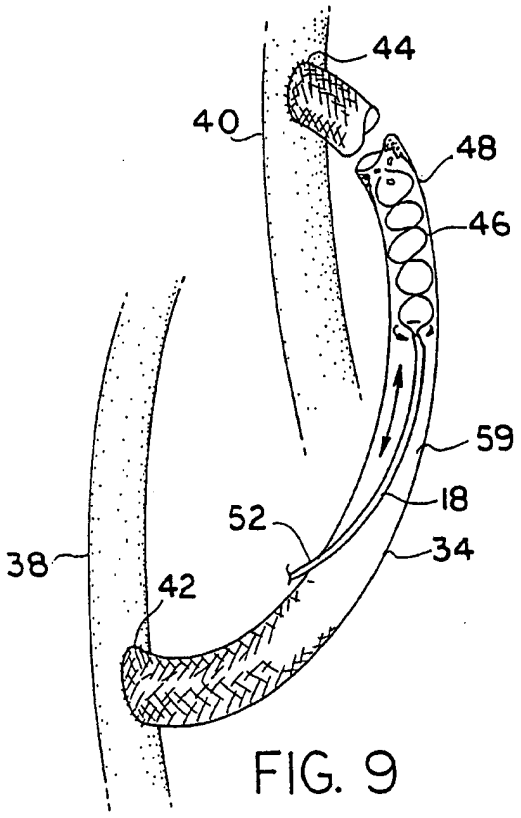

FIG. 9

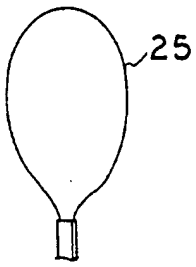

FIG. 10

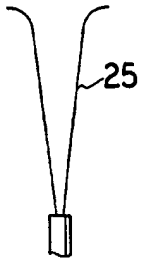

FIG. 12

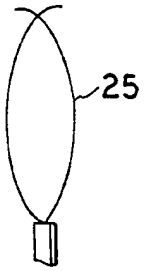

FIG. 11

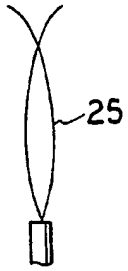

FIG. 13

INTERNATIONAL SEARCH REPORT

Int. ational Application No
PCT/US 98/15156

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimumdocumentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category ³	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 177 782 A (ADVANCED TECHNOLOGY LABORATORIES) 16 April 1986 cited in the application see page 4, line 2 - line 31 see page 5, line 34 - page 6, line 4 see page 9, line 29 - page 10, line 3; figures 1,4	1-5
A	DE 89 00 494 U (SCHNEIDER) 2 March 1989 see page 6, line 24 - page 7, line 4; figure 1	4
A	EP 0 452 631 A (OSYPKA) 23 October 1991 see abstract; figures 1,2	1-5
A	US 4 883 460 A (ZANETTI) 28 November 1989 see abstract see column 6, line 36 - line 45; figure 1	1,5

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

³ Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of theinternational search	Date of mailing of the international search report
28 October 1998	04/11/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Moers, R

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INTERNATIONAL SEARCH REPORT

Inte ational Application No
PCT/US 98/15156

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 709 110 A (INTERVENTIONAL TECHNOLOGIES) 1 May 1996 see abstract; figure 4	1,5
A	US 5 248 296 A (ALLIGER) 28 September 1993 see abstract; figure 1	1,5

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

In. .ational Application No
PCT/US 98/15156

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 177782 A	16-04-1986	CA 1266597 A	13-03-1990
		JP 1841267 C	25-04-1994
		JP 61068036 A	08-04-1986
		US 4646736 A	03-03-1987
DE 8900494 U	02-03-1989	NONE	
EP 452631 A	23-10-1991	DE 4012649 A	31-10-1991
		AT 114949 T	15-12-1994
		DE 59103739 D	19-01-1995
US 4883460 A	28-11-1989	NONE	
EP 709110 A	01-05-1996	US 5524635 A	11-06-1996
		AU 693178 B	25-06-1998
		AU 2053295 A	02-05-1996
		CA 2151621 A	25-04-1996
		JP 8126646 A	21-05-1996
US 5248296 A	28-09-1993	WO 9414382 A	07-07-1994